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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CANELLA, KAREN A	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/081,348	CUSSENOT ET AL.	
	Examiner	Art Unit	
	Karen A Canella	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *4-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3/26/2002
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgment is made of applicants election with traverse, of Group I, drawn to an established cell line and a non-human animal carrying said cell line. The traversal is on the grounds that the restriction is improper because it would not be undue burden to the examiner to search all the claims. This has been considered but not found persuasive. The restriction requirement was set forth as below:

Group I, drawn to an established cell line and a no-human animal carrying said cell line is related to Group II, drawn to a method for identifying a substance likely to treat tumor of the prostate comprising administering said substance to the non-human animal of Group I, as product and method of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the established cell line of Group I can be used in an in vitro assay for screening test substances.

Group III, drawn to an anti-PSM-12 antibody and a coupling product between said antibody a compound of therapeutic or diagnostic interest, is related to the method of Group IV, drawn to the use of the anti-PSM-12 antibody in a targeting process of tumor cells of the prostate, as product and method of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibody of Group III can be used in a process to make an anti-idiotypic antibody.

The products of Groups I and III are structurally and functionally different, made by different methods and used in different methods. The examination of both product would require different searches in the U.S. patent shoes. Further, the literature search, would not be co-extensive for either of the product groups.

The methods of Groups II and IV have different method objectives, different method steps and use different reagents and parameters. Again, each search would require a different search in the U.S. patent shoes and the literature. Neither search would be co-extensive.

Accordingly, undue burden would be involved in the search for all the of the instant inventions. The restriction requirement is deemed proper and adhered to. The restriction is hereby made FINAL.

2. Claims 1-28 are pending. Claims 15-28, drawn to non-elected inventions, are withdrawn from consideration. Claims 1-14 are examined on the merits.

Specification

3. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure as amended by the request filed on February 22, 2002 to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

Claim Objections

4. Claims 4-14 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot serve as the basis for another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 4-14 not been further treated on the merits.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "being likely to be grafted". It is unclear whether the actual successful grafting of the tumor is a specific embodiment of the claim. Further, the metes and bounds of "being likely to be grafter" cannot be determined relative to "being grafted". For purpose of examination, the instant claim will be examined with and without the criterion of an actual demonstration of successful grafting in an animal.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Weijerman et al (Cancer Genet Cytogenet, 1997, Vol. 99, pp. 108-115) as evidenced by the abstract of Weijerman et al (Urology, 1998, Vol. 51, pp. 657-662).

Claim 1 is drawn to a cell line obtained after separation and putting into culture of a spontaneous prostatic tumor existing in a first animal, characterized by containing the antigens recognized by anti-PSMA antibodies and having a karyotype of at least 60 chromosomes. Claim 2 embodies the cell line of claim 1, wherein the anti-PSMA antibody is the PSM-P12 antibody having the CNCM Accession No. I-2280.

Weijerman et al (1997) discloses the cell line, CA-HPV-10, which originates from a high grade human prostate cancer specimen (abstract), thus fulfilling the specific embodiment of claim 1, drawn to a spontaneous prostatic tumor. Weijerman et al (1997) discloses the modal number of 72, having a range of 69-75 (page 110, second column, lines 6-9), thus fulfilling the specific embodiment of claim 1 specifying at least 60 chromosomes. The abstract of Weijerman et al (1998) discloses that PSMA was detected in the CA-HPV-10 cell line by RT-PCR. Thus,

the CA-HPV-10 cell line disclosed by Weijerman et al (1997) has the inherent property of expressing PSMA and would thus fulfill the specific embodiment of claim 1 specifying that the cell lines contains antigens recognized by human anti-PSMA antibodies or the PSM-P12 antibody of claim 2.

9. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Gibas et al (Cancer Genet Cytogenet, 1984, Vol. 11, pp. 399-404) as evidenced by Israeli et al (Cancer Research, 1994, Vol. 54, pp. 1807-1811) and the abstract of Mitchell et al (BJU Int., May 2000, Vol. 85, pp. 932-944).

The specific embodiments of claim 1 and 2 are set forth above. Claim 3 embodies the methods of claims 1 or 2 wherein the cell line carries antigens recognized by anti-cytokeratin 19 and vimentin.

Gibas et al disclose that the LNCap cell line comprises cells which have at least 60 chromosomes (Figure 1). Israeli et al discloses that the LNCap cell line stains intensely with the anti-PSMA antibody 7E11-C5.3, thus fulfilling the specific embodiment of claim 1 regarding antigens which bind to a anti-PSMA antibody and claim 2 regarding binding to the anti-PSMA antibody, PSM-P12. The abstract of Mitchell et al discloses that the LNCap cell line was positive for cytokeratin-19 and positive for vimentin.

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
Cussenot et al (Experimental Cell Research, 1994, Vol. 214, pp. 83-92).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571)272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.
11/29/2004